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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,308	01/24/2002	George Eustace Joannou	JOANNOU	8120

7590 01/16/2003

Barnes & Thornburg
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Indianapolis, IN 46204

EXAMINER
OWENS, AMELIA A

ART UNIT	PAPER NUMBER
1625	7

DATE MAILED: 01/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,308	JOANNOU, GEORGE EUSTACE	
	Examiner	Art Unit	
	Amelia A. Owens	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,2,10,12-18 and 20-23 is/are rejected.

7)☒ Claim(s) 3-9,11 and 19 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

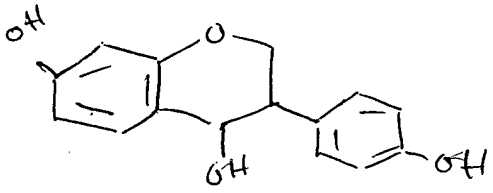
Claims 1-23 are pending. No drawings were filed with the application.

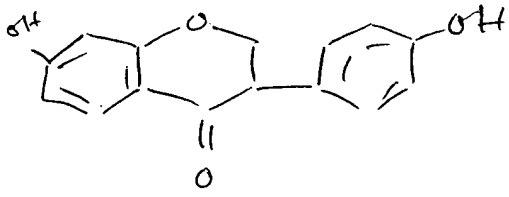
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 10, 12-18, and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Waehaelae et al (CA 127:307275).

Waehaelae et al teach compounds according to the invention. See abstract. The compounds are isoflavones having anticancer activity.

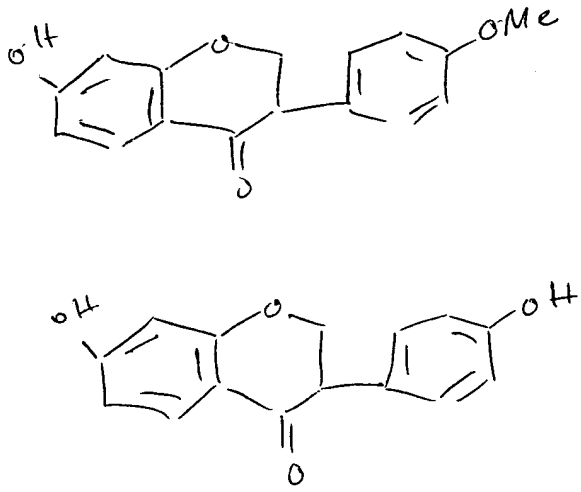


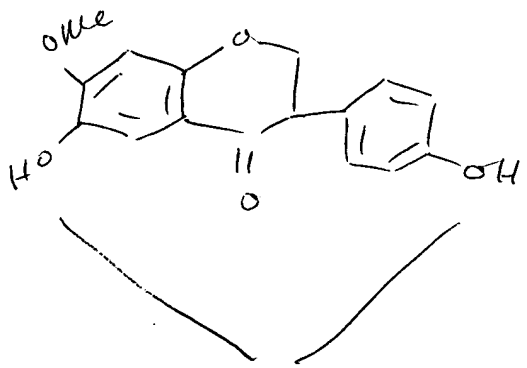


Claims 3-9, 11, 19 are not included because they are not taught or fairly suggested by the reference.

Claims 1, 2, 10, 12, 15 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bulut (CA 118:124232).

Bulut teach compounds according to the invention. See abstract. The compounds are isoflavones.





These positions may also be OMe.

Claims 3-9, 11, 13-14, 16-22 are not included as they are not taught or fairly suggested by the reference.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-18 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chem Abs. 128:164027 and WO 98/21946 (provided by applicant).

Chem Abs teaches the claimed compounds in the treatment of diseases associated with oxidant stress, inflammatory diseases, menopausal syndrome and cancer.

WO 98/21946 teaches compounds according to the invention to treat menopausal syndrome, hormone-dependent conditions and cancer.

One of ordinary skill in the art would be motivated to use compounds according to the references as they place the invention before the artisan.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-18 and 20-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in In re Wands (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of

direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill off those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The disclosure of the present invention is a method of treating cancer in a human wherein the claimed compound is administered either alone to a subject. One should be able, from reading of the claims, determine what that claim does or does not encompass. Why? Because that claim preclude others from making, using, or selling that compound for 20 years. Therefore, one must know what tumors are being treated.

In the pharmaceutical area, declarations under 37 CFR 1.132 are often employed to set forth the advantage or pharmacological activity of a particular compound. It is well known that compounds can treat a variety of tumors. Paclitaxel, for example can treat breast and ovarian cancer. The claims as set forth in the specification applicants are purporting to treat 'cancer' in the generic sense. Applicant should not be able to preempt future work of others by means of claims to a generic concept.

The written description is considered inadequate here in the specification. Conception of the intended tumors should not be the role of the reader. Applicant

should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely and invitation to experiment. How can applicants regard as their invention an inexact concept? The breadth of which they could not have possibly check out with representative exemplification.

The amount of guidance necessary to perform applicant's invention would result in undue experimentation because the skilled artisan would be forced to randomly test numerous cancers to determine which ones, if any, could be treated by administering the claimed compounds alone. Hence, the amount of guidance present in the specification fails to present the necessary instruction to determine what cancers are encompassed by the claims.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 17, 18, 21 and 22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims directed to use have been held to be non-statutory. Note Clinical Products v. Brenner 149 USPQ 475.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 703-308-4707. The examiner can normally be reached on Monday - Friday from 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan L. Rotman can be reached on 703-308-1235. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Amelia A. Owens
Primary Examiner
Art Unit 1625